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03/21/2006

Dariusz Behnam

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EXAMINER

BAEK, BONG-SOOK

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,918	Applicant(s) BEHNAM, DARIUSH	
	Examiner BONG-SOOK BAEK	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/11/2006 and 10/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-17 are currently pending.

Election/Restrictions

Applicants' election of group I drawn to a composition and election of the following species: dihydrolipoic acid as the species in claim 4 and safflower oil as the species in claim 5, in the reply filed on 8/8/2008 are acknowledged. The election was made without traverse.

Claims 13-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Claims 1-12 and 16-17 are under examination in the instant office action.

Priority

The instant application is a 371 of PCT/EP05/08940 filed on 08/18/2005 and claims benefit of foreign application filed on 08/18/2004. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of foreign application has been submitted on 03/21/2006.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 08/18/2005.

Information Disclosure Statement

Signed and initialed copies of the information disclosure statements (IDS) filed on 9/11/2006 and 10/16/2006 are enclosed in this action. The first non-patent literature reference (AG) listed in the IDS filed on 10/16/2006 was not considered because it is not written in English.

Claim objections

Claims 2-12 and 16-17 are objected because of the following informalities: typographical errors. The terms "Concentrate" in line 1 of claims 2-12 and 16-17 and "ubichinon" in the line 1 of claim 1 and line 2 of claim 7 should be corrected to --The concentrate-- and --ubiquinone--, respectively. Also, Q₁₀ should be added after "ubichinon" in line 2 of claim 7 and the term "Q₁₀" in line 3 of claim 8 and line 2 of claims 9-12 should be corrected to --ubiquinone Q₁₀--. In addition, the same typographical errors and other misspellings should be corrected in the specification.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim 8 contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant claim 8, the composition consists of about 85 w/w % of the polysorbates, about 3.3 w/w % of Q₁₀, about 4 w/w % of α -lipoic acid and about 10 w/w % of triglycerides, which sums up more than 100 % (102.3%), which is not enabled.

Claims 1-3 and 5-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Regarding the requirement for adequate written description of chemical entities, Applicant’s attention is directed to MPEP §2163. In particular, *Regents of the University of*

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California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, “not a mere wish or plan for obtaining the claimed chemical invention.” *Elli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office (“PTO”) Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 “Written Description” Requirement (“Guidelines”), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,” including, *inter alia*, “functional characteristics when coupled with a known or disclosed correlation between function and structure...” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Elli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

The claims recite α -lipoic acid derivatives. It cannot be determined what derivatives are encompassed by the derivatives since there is no definition of the α -lipoic acid derivatives in the specification. As such, it is not apparent that the Applicants were actually in possession of, and intended to use within the context of the present invention, the compounds defined by the α -lipoic acid derivatives, at the time the present invention was made.

Claim Rejections - 35 USC § 112, 2nd paragraph

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

Claim 1 recites the limitation "one or more emulgators with HLB value between 9 and 19 permitted according to the food or drug law". Since the food or drug law constantly changes, it is unclear which emulgators are included or not and thus it renders the claim indefinite.

Claims 1-12 and 16-17 are rejected because they depend from claim 1; thus incorporates its limitation.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant claim 8, the composition consists of about 85 w/w % of the polysorbates, about 3.3 w/w % of Q₁₀, about 4 w/w % of α -lipoic acid and about 10 w/w % of triglycerides, which sums up more than 100 % (102.3%). It is inconsistent with known scientific knowledge, thus it renders the claim indefinite.

Claims 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16-17 recite that the concentrate of claim 1 is added to non-alcoholic drinks or food stuff. In the instant claim 1, the water-free concentrate consists of four components. Since the phrase "consisting of" is used, additional component cannot be added,

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thus the scope of the claim 1 is narrower than those of claims 16-17. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-5 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,300,377 (Issue Date: 10/9/2001).

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The instant invention is drawn to a water-free concentrate consisting of ubiquinon Q₁₀ (ubiquinone Q₁₀), a medium-chained triglyceride or triglyceride mixture (elected species: safflower oil), α -lipoic acid and/or its derivatives (elected species: dihydrolipoic acid), as well as one or more emulgators with HLB value between 9 and 19 permitted according to the food or drug laws, preferably a polysorbate 20 and/or polysorbate 80 (claims 1-5). In other embodiments, the concentrate according to claim 1 is added to a non-alcoholic drink in the ratio of one part of the concentrate to about 0.1 to up to about 5,000 parts of the drink (claim 16) and the concentrate according to claim 1 is added to a milk product, vegetable oil or a similar foodstuff in the ratio of one part of the concentrate to about 0.1 to up to about 500 parts of the foodstuff (claim 17).

US Patent 6,300,377 discloses a composition comprising an effective amount of coenzyme Q₁₀ (ubiquinone Q₁₀), a polysorbate surfactant such as polysorbate 80 (emulgator), vegetable oil such as safflower oil or triglyceride in combination with other bioactive agents such as reduced α -lipoic acid (DHLA: dihydrolipoic acid) (column 1 line 64-column 2, line 19; column 6, lines 16-28 and lines 42-48). The reference is silent about HLB value of polysorbate 80, however polysorbate 80 as one of preferable emulgators of the instant invention inherently has HLB value between 9 and 19 permitted according to the food or drug laws. The reference also discloses a composition consisting of coenzyme Q₁₀ (ubiquinone Q₁₀), polysorbate 80 (emulgator), tributyrin (emulgator), medium chain triglycerides and vitamin E as one of the preferable embodiments (column 12, example 1 and column 3, lines 1-5). Since α -lipoic acid and vitamin E are preferable examples of other bioactive agents for use in the reference, vitamin E can be substituted with α -lipoic acid as other bioactive agent in that example. In addition, the instant composition can have more than one emulgator and an additional emulgator does not

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have to be a polysorbate since a emulgator consists of a polysorbate as recited in the instant claim 2. US Patent 6,300,377 further teaches that compositions comprising ubiquinone Q₁₀ and α -lipoic acid are particularly useful for influencing glucose metabolism and treating diabetes (column 7, lines 28-33). Furthermore, the term surfactant is used as an equivalent of emulsifier (emulgator) in the reference (column 2, line 66-column 3, line 6) and there is no water content in the exemplary composition (column 12, example 1 and 2), which means that the composition is water- free. Thus, these teachings read on all the limitations of claims 1-5.

Since the instant invention is directed to a composition, an intended use recited in claims 16-17, does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. See MPEP 2111.02: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As such, the instant claims 1-5 and 16-17 are anticipated by US patent 6,300,377.

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2) Claims 1-4 and 16-17 are rejected under 35 U.S.C. 102 (e) as being anticipated by US patent application publications 2005/0260752 (publication date: 11/24/2005, filing date: 4/1/2003).

US Patent publication 2005/0260752 discloses a composition comprising an effective amount of coenzyme Q₁₀ (ubiquinone Q₁₀), a polysorbate such as polysorbate 80 (emulgator), medium chain triglyceride in combination with the secondary bioactive agents such as reduced α -lipoic acid (DHHLA: dihydrolipoic acid) (abstract; p1, [0005]; p2, [0022]; p3, example 1). The reference is silent about HLB value of polysorbate 80, however polysorbate 80 as one of preferable emulgators of the instant invention inherently has HLB value between 9 and 19 permitted according to the food or drug. The reference also discloses a composition consisting of coenzyme Q₁₀ (ubiquinone Q₁₀), Tween 80 (polysorbate 80, emulgator), Span 20 (emulgator), medium chain triglycerides and vitamin E as one of the preferable embodiments (p3, example 1). Since α -lipoic acid and vitamin E are preferable examples of the secondary bioactive agents for use in the reference, vitamin E can be substituted with α -lipoic acid as the secondary bioactive agent in that example. In addition, the instant composition can have more than one emulgators and an additional emulgator does not have to be a polysorbate since a emulgator consists of a polysorbate as recited in the instant claim 2. Furthermore, there is no water content in the exemplary composition (p3, example 1), which means that the composition is water-free. Therefore, these teachings read on all the limitations of claims 1-4.

Since the instant invention is directed to a composition, an intended use recited in claims 16-17, does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but

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must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. See MPEP 2111.02: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As such, the instant claims 1-4 and 16-17 are anticipated by US patent 6,300,377.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1 and 6-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US patent 6,300,377.

US patent 6,300,377 teaches a water-free composition consisting of all ingredients recited in the instant claim 1 as stated above in the 102 rejection.

In the instant claims 6 and 7, the ratio by weight of the polysorbate to the sum of the proportions by weight of the remaining ingredients amounts to about 4:1 to about 5.5:1 in the

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concentrate and the ratio by weight of ubiquinone Q₁₀, to α -lipoic acid lies between about 1:1 and about 1:4 in the concentrate. Claims 7-12 recite different embodiments of the compositions consisting of ubiquinone Q₁₀ (about 3.3, 5, 4, or 2 w/w %), polysorbates (about 85, 81, 82, or 84 w/w %), α -lipoic acid (about 4, 10, 8, or 9 w/w %) , and triglycerides (about 10, 4, 6, or 5 w/w %), each of which have just a little different percentage of each component (claims 8-12).

US Patent 6,300,377 further teaches that the preferable ranges of ubiquinone Q₁₀, a primary surfactant, a glyceryl ester which can be used as surfactant in combination with the primary surfactant, a triglyceride, and a bioactive agent such as α -lipoic acid are from about 0.05% to about 15%, from about 20% to about 50%; from about 5% to about 30%, from about 0.15% to about 35%, and 0.01% to about 25% by weight of the composition, respectively (column 7, lines 48-column 8, lines 1-5). It does not specifically teach the ratio of the polysorbate to the sum of the proportions by weight of the remaining ingredients and the specific percentages of ubiquinone Q₁₀, a polysorbate , α -lipoic acid, and triglycerides (about 10, 4, 6, or 5 w/w %),.

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize the percentage or ratio of ubiquinone Q₁₀, a polysorbate , α -lipoic acid, and triglycerides from the ranges taught by US patent 6,300,377. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at

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1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). In the instant case, the claimed and disclosed ranges or percentage fall within the ranges of the prior art and the prior art suggests the percentage close to those claimed such that optimization is deemed well within the skill of the practitioner.

2) Claims 1-12 and 16-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US patent application publication 2003/0165438 (publication date: 9/4/2003) in view of US patent 6,277,842 (issue date: 8/21/2001) and US patent application publication 2004/0081670 (publication date: 4/29/2004).

US 2003/0165438 teaches a essentially water-free composition containing ubiquinone Q₁₀, an emulsifier such as polysorbate 80, light oil containing medium chain triglyceride such as safflower oil (abstract; claims 2 and 4). US 2003/0165438 further teaches that the preferable content of ubiquinone Q₁₀, safflower oil and emulsifier such as polysorbate 80, light oil containing medium chain triglyceride are about 3%, about 8-20%, more preferably 12-15%, and about 50-85% by weight of the composition, respectively (claims 3, 5, and 8). Also, it further discloses that the ratio by weight of the polysorbate to the sum of the proportions by weight of the remaining ingredients is about 5.5:1 (p9, example 1). It does not specifically teach α -lipoic

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acid in combination with ubiquinone Q₁₀ and some of specific percentage of ubiquinone Q₁₀, a polysorbate, α -lipoic acid, and triglycerides.

US 2004/0081670 teaches water-soluble concentrates of an active substance such as ubiquinone Q₁₀ or α -lipoic acid with emulsifier such as polysorbate and triglyceride such as linoleic acid and a method of making the concentrate (abstract, [0012], example 1, and example 8, claims 1, 17-18). It further discloses that a concentrate containing an active substance such as ubiquinone Q₁₀ or α -lipoic acid is prepared by heating and stirring with solubilizer such as a polysorbate, preferably polysorbate 80 and additionally adding linoleic acid while heated and then cooling down (claim 1 and examples 1 and 8). It further teaches that the active substance content is approximately 20% or less (claim 23).

US patent 6,277,842 teaches a method for promoting weight and fat loss, comprising coadministering α -lipoic acid, ubiquinone Q₁₀, L-carnitine, chromium, creatine, niacin, pyruvate, riboflavin, and thiamine. It further teaches that lipoic acid is a major intracellular antioxidant, and component of key enzymes in the citric acid cycle and ubiquinone Q₁₀ accepts the hydrogen atoms from breakdown of the dietary fuels and utilizes them for cellular energy production (abstract). Also, it discloses that supplemental lipoic acid maintains a normal ratio of reduced –to-oxidized coenzyme Q₁₀ (column 3, lines 28-29). In addition, the preferable effective amount of α -lipoic acid and coenzyme Q₁₀ are between 30 mg and 6000 mg and between 10 mg and 2400 mg, respectively (column 3, lines 59-63).

It would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to add α -lipoic acid to the ubiquinone Q₁₀ composition taught by US 2003/0165438 for reducing weight without side effect, which the alleged use of the instant

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invention with a reasonable expectation of success because of the following reasons: US

2004/0081670 teaches α -lipoic acid concentrate is prepared in the similar way as ubiquinone Q₁₀ concentrate. US patent 6,277,842 teaches that α -lipoic acid and ubiquinone Q₁₀ are effective for promoting weight and fat loss and coexistence of α -lipoic acid and ubiquinone Q₁₀ are beneficial for each other. Thus, one of ordinary skill in the art at the time of invention was made would have been motivated to make a concentrate composition containing both α -lipoic acid and ubiquinone Q₁₀ as taught by US 2003/0165438 for reducing weight or treatment of obesity.

Also, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention was made to optimize the specific percentage or ratio of ubiquinone Q₁₀, a polysorbate, α -lipoic acid, and triglycerides from the ranges taught by US 2003/0165438 and US 2004/0081670 and the effective amounts of α -lipoic acid and coenzyme Q₁₀ taught by US patent 6,277,842. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of

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molecular weight or molar proportions.). In the instant case, the claimed and disclosed ranges or percentage fall within the ranges of the prior art and the prior art suggests the percentage close to those claimed such that optimization is deemed well within the skill of the practitioner.

Since the instant invention is directed to a composition, an intended use recited in claims 16-17, does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. See MPEP 2111.02: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Statutory Double Patenting Rejection

Claims 1-5, 7-12, and 16-17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5, 7-8, 10-13 and 18-19 of copending application No.11/392957. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BONG-SOOK BAEK
Examiner, Art Unit 4161

Bbs

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161